

MANUFACTURER DECLARATION

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TO WHOM IT MAY CONCERN

Recently, several new SARS-CoV-2 mutations have been detected around the world. The observed mutations mainly affect the spike protein (protein S) of the virus, which plays a key role in the process of receptor recognition and cell fusion. This explains why the virus became significantly more infectious from these mutations.

The AMP SARS-CoV-2 Ag Rapid Test detects the nucleocapsid protein (protein N) antigen, which is unaffected by recent mutations. Therefore, the new mutations, like many others that have occurred before already, have no impact on the performance of the test and the reliability of the test results.

This has also been verified by clinical evaluation of samples confirmed to contain the mutations B.1.1.7 (Alpha or UK variant), B.1.351 (Beta or South African variant), P.1 (Gamma or Brazilian variant), B.1.617 (Delta = Indian variant), B.1.167.1 (Kappa variant) and C.37 (Lambda = Peruvian variant). These practical tests evidenced, that the performance of the test is not affected by mutations.

AMEDA Labordiagnostik GmbH


Gerald Herfort


AMEDA Labordiagnostik GmbH
Krenngasse 12 - 8010 Graz - Austria
Tel. +43 - 316 - 69 80 69, Fax ext. - 12

COO

AMEDA Labordiagnostik GmbH